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September 2, 2021

VIA ECF

Hon. Lois H. Goodman, U.S.M.J.
U.S. District Court for the District of New Jersey
Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street
Trenton, New Jersey 08608

***Re: Janssen Products, L.P., et al. v. eVenus Pharmaceuticals
Laboratories Inc., et al., No. 3:20-cv-09369 (ZNQ)(LHG)***

Dear Judge Goodman:

We, along with Kramer Levin, represent Plaintiffs Janssen and Pharma Mar. Consistent with Your Honor's direction, this letter is submitted as a joint submission with Defendants Sun and Natco who are represented by Rivkin Radler and Knobbe Martens.

The parties are writing regarding a dispute that arose in the preparation of the Joint Claim Construction and Prehearing Statement (JCC), which will require the Court's assistance to resolve. The parties have met and conferred a number of times on the issue in writing and by phone, including on a call this past Wednesday as required by Your Honor's August 27 Order.

Sun and Natco object to Plaintiffs' proposed claim construction as untimely. As described below, the parties disagree how this dispute should be presented to and resolved by the Court. Prior to filing formal motions, the parties seek the Court's guidance on how to proceed. The parties are filing the JCC today, September 2, 2021.

Sun and Natco's Position:

Under the District of New Jersey's Local Patent Rules ("DNJ LPR") and this Court's schedule, the parties were required to **simultaneously** exchange their proposed claim constructions on August 5, 2021. On August 5, pursuant to DNJ LPR 4.2(a), the parties simultaneously exchanged their proposed claim constructions of the disputed terms at issue, including the term "single active anti-tumor compound." In their disclosure, Plaintiffs proposed that "single active anti-tumor compound" should be construed as "plain and ordinary meaning."

After the August 5 exchange, Sun and Natco met and conferred with Plaintiffs several times to try to narrow the claim construction disputes for the Court. In fact, as

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reflected in the JCC, the parties did reach an agreement on the disputed term of the '051 Patent, which did, in fact, **narrow** the claim construction issues on that patent for the Court. However, during those meet and confers, Plaintiffs repeatedly questioned counsel for Sun and Natco regarding their **non-infringement arguments** for the '557 Patent and even stated that "we have re-reviewed Natco's and Sun's non-infringement contentions after the call yesterday." But Plaintiffs weren't trying to narrow the claim construction issues on the '557 Patent for the Court. Instead, Plaintiffs were trying to better understand Sun and Natco's **non-infringement arguments** so Plaintiffs could, well after the deadline to propose constructions, completely rewrite their proposed construction of "single active anti-tumor compound" to try to cover Sun and Natco's product. And that rewriting is exactly what Plaintiffs did.

On August 18 at 11pm ET the night before the parties were required to exchange opposition evidence pursuant to DNJ LPR 4.2(c), **and weeks after their proposed construction was due**, Plaintiffs sent an email purporting to amend their proposed construction by, for the very first time, changing their construction to be "Plain and ordinary meaning, *i.e.*, **no construction, or if construed then, 'a single compound providing the anti-tumor activity of the composition.'**" The following table shows Plaintiffs' original proposed construction pursuant to DNJ LPR 4.2(a) compared to Plaintiffs' untimely and substantively changed proposed construction.

Disputed Term	Plaintiffs' Aug. 5 LPR 4.2(a) Construction	Plaintiffs' Aug. 18, 2021 Proposed Construction
"single active anti-tumor compound"	"Plain and ordinary meaning"	"Plain and ordinary meaning, <u>i.e., no construction, or if construed then, 'a single compound providing the anti-tumor activity of the composition.'</u> "

Pursuant to DNJ LPR, to amend their proposed claim constructions, Plaintiffs were required to seek leave from the Court, and show good cause. *See* DNJ LPR 3.7 (emphasis added) ("**Amendment of any contentions, disclosures, or other documents required to be filed or exchanged pursuant to these Local Patent Rules may be made only by order of the Court upon a timely application and showing of good cause.**"). Plaintiffs cannot show good cause and have refused to seek

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leave to amend. In what appears to be a half-hearted attempt to show good cause and skirt the DNJ LPR, Plaintiffs try to recast their gamesmanship as a “clarification” of the plain and ordinary meaning; however, “clarifications” to claim construction after the due date are not allowed without leave of the court. Plaintiffs do not cite a single case to support their position that they can ignore the DNJ LPR. Next, Plaintiffs oddly try to blame Sun and Natco, stating that “Defendants finally provided clarification of their position in a way that allowed Plaintiffs to understand the gap between the parties and directly engage the issue.” However, Sun and Natco never “clarified their position” on claim construction during the meet and confers—Sun and Natco **always** maintained the exact same construction that was timely provided on August 5. If Plaintiffs’ statement refers to Sun and Natco’s non-infringement arguments, rather than claim construction, that statement is also untrue because Sun and Natco have **always** maintained that their product did not infringe since serving their non-infringement contentions **six months earlier**. Regardless, whatever Plaintiffs mean by “understand the gap” and “directly engage the issue,” that does not give them liberty to ignore the DNJ LPR’s requirements.

Plaintiffs’ reliance on the word “preliminary” in the DNJ LPR 4.2(a) title is misplaced. “Preliminary” refers to the parties’ timely proposals and the process to meet and confer to attempt to reach agreement to **narrow** the issues for the Court—nowhere in the DNJ LPR does it say that a party can change their construction to **broaden** the issues for claim construction. Indeed, the DNJ LPR have strict rules for timing of claim construction disclosures and exchanges. If Plaintiffs were correct, then every single time a party changed their construction during the claim construction process, the parties would have to go back, restart the clock and serve a new 4.2(b) disclosure of supporting evidence and then 14 days later a new 4.2(c) disclosure of opposition evidence to that new construction. Thus, Plaintiffs’ reading of the rules cannot be correct nor do Plaintiffs cite a single case in support. Likewise, Plaintiffs’ reliance on DNJ LPR 4.2(c) to somehow support their alleged right to propose an entirely new construction, well after the deadline to disclose claim constructions, without seeking leave of the Court is misplaced. DNJ LPR 4.2(c) simply states that “the parties shall exchange an identification of all intrinsic and extrinsic **evidence** that each party intends to rely upon to oppose any other party’s proposed construction.” 4.2(c) relates to opposition **evidence**, and it does not grant a party the right to propose a new construction, for the first time, weeks after the deadline under DNJ LPR 4.2(a).

Importantly, the DNJ LPR were adopted to prevent the kind of shifting sands approach to litigation evidenced by Plaintiffs’ attempt to change their claim construction well after the deadline. That timing alone is highly prejudicial to Sun and Natco. But even more prejudicial to Sun and Natco is that Plaintiffs gamed the *Markman* process

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and the DNJ LPR by (i) obtaining Sun and Natco's timely proposed construction and supporting evidence on August 5, and studying that proposal and evidence for weeks, (ii) then asking extensive questions of Sun and Natco regarding their **non-infringement positions** during meet and confers that were **supposed to narrow the claim construction issues** for the Court, and (iii) admittedly "re-reviewing" Sun & Natco's non-infringement contentions (which were served over 6 months ago), all before carefully crafting and providing their new and untimely "alternative construction" on August 18. It is highly prejudicial to Sun and Natco for Plaintiffs to present no construction during the parties' mutual exchanges under the DNJ LPR 4.2(a), only to adopt a new "alternative construction" after getting a "sneak peek" at Sun and Natco's construction and evidence, and cross-examining Sun and Natco's non-infringement contentions during meet and confers designed to narrow the issues for *Markman*, not broaden them. If Plaintiffs are allowed to move forward with their new and untimely "clarification" here, the DNJ LPR's mutuality of claim construction exchanges would become meaningless, and the prejudice to Sun and Natco would be left unresolved.

Plaintiffs claim that "the parties agreed to a 10 day extension of the date for submission of the JCC, during which Defendants could have attempted to cure any perceived prejudice but chose not to." This statement is incorrect for at least two reasons. First, any "additional time" would not cure the prejudice Sun and Natco suffer as discussed above, which was caused by Plaintiffs' "sneak peek" approach. Second, the "additional time" was provided by Sun and Natco solely as a professional courtesy due to **Plaintiffs' representation** that "our clients are on holiday for the remainder of August, and we need until September 2 to respond" to finalize the JCC. It is beyond the pale that Plaintiffs asked for a 10 day extension of the JCC because of a "client holiday," only to use that professional courtesy provided by Sun and Natco as a sword in this letter.

On September 1, 2021, the parties met and conferred, and Plaintiffs stated that they would not be moving to amend their claim construction. Therefore, Sun and Natco intend to move to strike any references (in the JCC, in *Markman* briefing, and at the *Markman* hearing) to Plaintiffs' new, untimely, enlarged, and litigation-inspired claim construction. We understand that our motion to strike should be directed to Judge Quraishi. However, if our motion to strike instead should be directed to Your Honor, we respectfully request such guidance from the Court.

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Plaintiffs' Response:

The JCC identifies a single claim term for construction. Plaintiffs do not believe construction of this claim term, “[a] single active anti-tumor compound,”¹ is necessary, as its plain and ordinary meaning is clear on its face and from the use of the term in the context of the claims. Plaintiffs set forth their “Preliminary Claim Construction” pursuant to L. Pat. R. 4.2(a) as the “plain and ordinary meaning” and set forth their supporting evidence pursuant to L. Pat. R. 4.2(b). The eVenus Defendants do not seek construction of the term.

Prior to and after the initial exchange pursuant to L. Pat. R. 4.2(a), Plaintiffs pursued clarification of the Sun & Natco Defendants’ position in several email exchanges and meet and confers to understand why they were seeking construction of the term. On an August 17 meet and confer, the Sun & Natco Defendants finally provided clarification of their position in a way that allowed Plaintiffs to understand the gap between the parties and directly engage the issue. On August 18, Plaintiffs reiterated their position that, consistent with the plain and ordinary meaning of the term, it need not be construed, and further clarified that, if construed, it should be construed as “a single compound providing the anti-tumor activity of the composition.” Plaintiffs further asked if Defendants would agree to that construction to moot the dispute. The Sun & Natco Defendants did not respond, instead sending objections just before the scheduled L. Pat. R. 4.2(c) exchange of information. Plaintiffs’ disclosure pursuant to L. Pat. R. 4.2(c) on August 19 included the same information Plaintiffs had already provided to the Sun & Natco Defendants in advance of the exchange. The parties also conducted subsequent meet and confers pursuant to L. Pat. R. 4.2(d).

The Sun & Natco Defendants argue that Plaintiffs must move the Court pursuant to L. Pat. R. 3.7 to “amend” Plaintiffs’ L. Pat. R. 4.2(a) disclosure in order to include their timely L. Pat. R. 4.2(c) disclosure in the JCC. This has no basis in the Local Rules and is contrary to the purpose and design of L. Pat. R. 4.2, which allows the parties to narrow their dispute through the exchange of information. L. Pat. R. 4.2 expressly refers to all exchanges of proposed constructions and related evidence as “Preliminary” until the filing of the JCC. L. Pat. R. 4.3 further explains that evidence is properly included in the JCC if disclosed pursuant to L. Pat. R. 4.2(a) through 4.2(c), which is the case here. *See* L. Pat. R. 4.3(f) (“[a]ny evidence that is not identified under L. Pat. R. 4.2(a) through 4.2(c) **inclusive** shall not be included in the Joint Claim Construction and Prehearing

¹ The parties disagree on the term to be construed, with Plaintiffs’ proposed construction directed to “a single active anti-tumor compound” and the Sun & Natco Defendants’ proposed construction directed to “single active anti-tumor compound.”

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Statement”) (emphasis added). There is therefore no need to amend Plaintiffs’ Preliminary disclosures pursuant to L. Pat. R. 4.2(a) in view of their L. Pat. R. 4.2(c) disclosure.

The Sun & Natco Defendants argue that any modification or clarification of a proposed claim construction would necessarily result in a re-setting of the clock for all L. Pat. R. 4.2 disclosures—this is plainly not the case. The Rule is designed to encourage exchange of information so that the parties may reach an agreed construction, which is impossible under Defendants’ view that a party cannot clarify its proposed claim construction or engage directly on the issue without seeking to amend its L. Pat. R. 4.2(a) disclosure. Under Defendants’ erroneous theory, parties would need to move to amend their L. Pat. R. 4.2(a) disclosure in order to arrive at an agreed construction.

Plaintiffs are unaware of any decision in this District holding that a proposed construction disclosed under L. Pat. R. 4.2(c) is untimely or cannot be included in the JCC, or any decision requiring a party to amend a Preliminary claim construction provided under L. Pat. R. 4.2(a) when a construction was timely disclosed pursuant to L. Pat. R. 4.2(c). Nor would such a requirement to amend make sense in the context of a Rule designed to **promote** exchange of information in an effort to come to mutual agreement. Similarly, Plaintiffs are unaware of any court in this District striking a proposed claim construction provided under L. Pat. R. 4.2(c), nor would the Sun & Natco Defendants be able to meet their burden in moving to strike Plaintiffs’ good faith claim construction made without delay and without prejudice.

If the Court would like this issue briefed as a formal motion to consider the dispute or if the Court views amendment of Plaintiffs’ Preliminary disclosures under L. Pat. R. 4.2(a) as the appropriate course, Plaintiffs will make such a motion. Plaintiffs would also welcome an opportunity to resolve this dispute informally with the Court’s assistance.

Plaintiffs provided their clarification of the plain and ordinary meaning promptly as soon as they understood the nature of the dispute and sought to moot it, easily satisfying the requirement for good cause under L. Pat. R. 3.7 if amendment were required. Nor is there any prejudice to Defendants. The Sun & Natco Defendants were apprised of Plaintiffs’ position prior to Plaintiffs’ L. Pat. R. 4.2(c) disclosure, which contained the exact same information previously identified. In addition, at Plaintiffs’ request, the parties agreed to a 10 day extension of the date for submission of the JCC, during which Defendants could have attempted to cure any perceived prejudice but chose not to. Defendants therefore have already had two weeks to consider Plaintiffs’ clarification of their construction. Plaintiffs also offered Defendants additional time if they wanted to further consider the construction and to extend the deadline for filing the JCC. Defendants have refused any additional time. Defendants’ sole alleged prejudice is

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that Plaintiffs considered Defendants' position, asked questions about it, and reviewed information (at Defendants' suggestion) in Plaintiffs' possession in order to understand Defendants' position. This is not prejudice, but the intended conduct of the parties pursuant to L. Pat. R. 4.2.

Defendants' insistence that the parties consider claim construction in a vacuum, unrelated to any infringement issues, and that they are somehow prejudiced by consideration of infringement issues, is unfounded. Indeed, the Federal Circuit instructs the opposite and has "emphasized the importance of the context provided by an analysis of the accused device when ruling on claim construction and the problems presented by construing claims in the absence of such context." *Jang v. Boston Sci. Corp.*, 532 F.3d 1330, 1337 (Fed. Cir. 2008). Further, it is the Sun & Natco Defendants that seek to use their construction to read literal claim language out of the claim in order to try to advance a non-infringement theory where no credible one exists. Tellingly, the eVenus Defendants have not made any such arguments and do not seek any construction of the term.

The Sun & Natco Defendants have suffered no prejudice in view of proper consideration of infringement issues, Plaintiffs' timely disclosure pursuant to L. Pat. R. 4.2(c), the time that Sun & Natco have already had to consider Plaintiffs' disclosure, and the fact that the *Markman* hearing is four months away and opening briefs are not due for six weeks.

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The parties appreciate the Court's attention this matter.

Respectfully submitted,

/s/ Cynthia S. Betz

Cynthia S. Betz

cc: All counsel of record (via ECF)